

MAY - 2 2011

6. 510(K) SUMMARY

Applicant: Biosense Webster, Inc.
3333 Diamond Canyon Rd.
Diamond Bar, CA 91765
USA
Phone: 800-729-9010
Fax: 909-839-8804

Date: July 13, 2010

Contact Person: Balaka Das
Senior Specialist, Regulatory Affairs

Proprietary Device Name: Webster Duo-Decapolar Catheter

Common Device Name: Electrophysiology Mapping Catheter

Classification Name: Electrode Recording Catheter
(per 21 CFR 870.1220, Product Code DRF)

Predicate Device:

1. The Cordis Webster A20 Diagnostic Deflectable Tip Catheter (510(k) K953768)
2. The Webster CS Catheter with EZ Steer Technology (510(k) K090898 and K101345)

Manufacturing Facilities:

Biosense Webster, Inc.
15715 Arrow Highway
Irwindale, CA 91706 USA

Biosense Webster, Inc.
Circuito Interior Norte, #1820
Parque Industrial Salvacar
Juarez, Chihuahua MX 32599

6.1 Substantially Equivalent To:

The Webster Duo-Decapolar Catheter is substantially equivalent to:

1. The Cordis Webster A20 Diagnostic Deflectable Tip Catheter D-1097-442 (510(k) K953768)
2. The Webster CS Catheter with EZ Steer Technology D-1263-04 (510(k) K090898 and K101345)

6.2 Description of the Device Subject to Premarket Notification:

The Biosense Webster Duo-Decapolar Catheter, manufacturing part number D-1171-35, is designed for electrophysiological mapping of cardiac structures. The catheter has a high-torque 7 Fr shaft with a tip section containing 10 pairs of platinum-iridium electrodes that can easily be seen under fluoroscopy. The 10 pairs of electrodes are arranged in two sets of five with a spacing of 60 mm between the sets. The electrode spacing within each set is 2-8-2 mm. The D-1171-35 catheter facilitates simultaneous local electrograms due to the greater number of electrodes and its deflection capabilities. All of the electrodes may be used for recording and stimulation purposes.

Tip deflection is controlled at the proximal end by a tubular hand piece in which a piston slides. The piston in the handpiece is attached to an internal puller wire which changes the radius of the curvature. When the piston is pushed forward with the thumbknob, the radius of the curvature is reduced; when the thumbknob is pulled back, the radius of the curvature is increased until the tip section straightens. The high-torque shaft allows the plane of the curved tip to be rotated to facilitate accurate positioning of the catheter tip at the desired site.

The catheter has a bifurcated Pigtail Connector Subassembly at the proximal end of the hand piece that houses a pair of 10-pin circular connectors. This connector provides a means for the catheter to connect to an interface cable and allow interface of the catheter with standard recording equipment.

6.3 Indications for Use:

The catheter is indicated for electrophysiological mapping of cardiac structures; i.e., stimulation and recording only. In addition, the Webster Duo-Decapolar Catheter is designed to facilitate electrogram mapping in the atrial region of the heart and the coronary sinus.

6.4 Performance Data:

The design of the Webster Duo-Decapolar Catheter underwent extensive bench (mechanical, electrical and simulated use) testing. The catheter passed all testing in accordance with appropriate test criteria and standards. The catheter was assessed to be safe and effective for use in the coronary sinus based on an animal study performed with the similarly designed Webster CS Catheter with EZ Steer Technology.

6.5 Overall Performance Conclusions:

Based on the results of bench, and animal and studies performed it is concluded that the Webster Duo-Decapolar Catheter, part number D-1171-35, described in this submission is as safe and effective as the predicate devices for its indicated use.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room --WO66-G609
Silver Spring, MD 20993-0002

Biosense Webster, Inc.
c/o James Petrie
Regulatory Affairs Manager
3333 Diamond Canyon Road
Diamond Bar, CA 91765

MAY - 2 2011

Re: K101991
Trade/Device Name: Webster Duo-Decapolar Catheter D-1171-35
Regulation Number: 21 CFR 870.1220
Regulation Name: Electrode Recording Catheter
Regulatory Class: Class II (two)
Product Code: DRF
Dated: April 27, 2011
Received: April 28, 2011

Dear Mr. Petrie:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

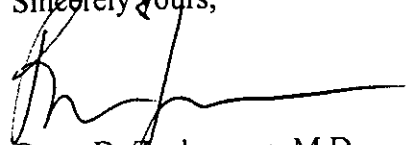
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CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

5. INDICATIONS FOR USE STATEMENT

510(k) No (if known): K 101991

Device Name: Webster Duo-Decapolar Catheter

Indications for Use:

The catheter is indicated for electrophysiological mapping of cardiac structures; i.e., stimulation and recording only. In addition, the Webster Duo-Decapolar Catheter is designed to facilitate electrogram mapping in the atrial region of the heart and the coronary sinus.

Prescription Use ✓
(Part 21 CFR 801 Subpart D)


AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE
IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K 101 991